UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/605,415	09/29/2003	Calum A. Macrae	10284-077001 / MGH	2414

2236

26161 7590 10/10/2006

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
NOBLE, MARCIA STEPHENS	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,415	MACRAE ET AL.	
	Examiner	Art Unit	
	Marcia S. Noble	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-70 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 8-24, 27-37, 40-45, 47-50, 52-55, 57, 58, and 60 drawn to a method of evaluating a test agent for the ability to modulate heart function comprising contacting a wild-type zebrafish with a test agent and determining changes in heart function, classified in class 800, subclass 3.

II. Claims 1, 6, 7, 20, 25, 26, 38-40, 46, 51, 52, 56, 59, and 61-64, drawn to a method of evaluating a test agent for the ability to modulate heart function comprising contacting a transgenic zebrafish or a fish with a genetic alteration with a test agent and determining changes in heart function, classified in class 800, subclass 3.

III. Claims 61-64, drawn to a method of evaluating a test agent for the ability to modulate heart function comprising contacting a genetically altered fish, by random mutagenesis, with a test agent and determining changes in heart function, classified in class 800, subclass 3.

IV. Claims 65-70, drawn to a nucleic acid of SEQ ID NO:1 encoding a fluorescent protein operabley linked to a heterologous coding sequence, a vector comprising said nucleic acid, and a host cell comprising said vector, classified in class 536 and 435, subclass 23.1 and 325.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different method step because they are testing a genetic component in II that is not present in I. The methods involving the transgenic are determining the impact of a drug in combination with the effect of a genetic manipulation and the use measurements of fluorescence as an indicator of heart function. The method with the wild type is testing a drug without measuring the effect of a genetic component and measures heart function using other parameters. Therefore, the starting materials are different (i.e.-transgenic vs wild-type zebra fish), the methods are different as disclosed above, and ultimately the outcome can be different.

3. Inventions I and III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different method step because they are testing a genetic component in III that is not present in I. The methods involving the genetically altered fish by random mutagenesis are determining the impact of a drug in combination with the effect of a random genetic alteration on heart function. The method with the wild type is testing a drug without measuring the effect of a genetic component. Therefore, the starting materials are different (i.e.- randomly, genetically-altered zebra fish vs wild-type zebra

fish), the methods are different as disclosed above, and ultimately the outcome can be different.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of group I uses wild-type zebrafish and does not encompass any use the nucleic acids, vectors, or cells of group IV. Furthermore, the method of group I do not result in the products of group IV.

5. Inventions II and III are distinct. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different method step because two different types of genetic manipulation are being utilized. The methods involving the genetically altered fish by random mutagenesis is a random mutagenesis process resulting a in a random mutation in the genome of the fish. It can result in a mutation of a gene, regulatory factor, etc; however, the factor being mutated is random and at least initially unknown. In contrast, transgenic fish results in a targeted mutation of a known gene or insertion of a known gene. Therefore the method steps that result in the genetic manipulation are done by different means and therefore are different steps. Furthermore, the starting materials are different (i.e.- randomly, genetically-altered zebra fish vs transgenic zebra

fish), the methods are different as disclosed above, and ultimately the outcome can be different.

6. Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the vector of group IV can be used in other methods than that of group II, such as transfecting cell for cell culture assays. Similarly the method of group II can utilize other nucleic acids and vectors to produce transgenic fish for use in the instant method.

7. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the method of group III uses a randomly, genetically-altered fish and does not encompass any use the nucleic acids, vectors, or cells of group IV. Furthermore, the method of group III does not result in the products of group IV.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their

recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CRF 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcia S. Noble whose telephone number is (571) 272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcia S. Noble

AU1632